AliveCor

AliveCor® Mobile ECG

User Manual for Android

NOTE: For the current information on your product please visit
http://www.alivecor.com/user-manual

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AliveCor

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1. PRODUCT DESCRIPTION

The AliveCor® Mobile ECG is a mobile, clinical-quality electrocardiogram (ECG) recorder. The duration of the recording is established by the AliveECG App with a default setting of 30 seconds and a maximum time of 5 minutes. The software application can store thousands of recordings on your smartphone or tablet and these recordings are also accessible to authorized users on AliveCor, Inc. (AliveCor) servers (www.alivecor.com).

Patients with known or suspected heart conditions and health conscious individuals can use the AliveCor Mobile ECG to record an ECG daily or whenever they are feeling symptoms, and share their recordings with their physician. Medical professionals can use the AliveCor Mobile ECG to quickly assess rate and rhythm, screen for arrhythmias, and remotely monitor and manage their patients who use the AliveCor Mobile ECG.

The device consists of three components:

1. The Mobile ECG, which attaches to your compatible smartphone or tablet and has electrodes to transmit ECG rhythms to the smartphone or tablet.
2. The *AliveECG* mobile application (*AliveECG* app) is used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
3. A user-supplied compatible smartphone or tablet.

CAUTION: The AliveCor Mobile ECG has features that are only available to users who are under the care of a physician. These features are available to prescription users only.

The Mobile ECG enables users to:

- Collect and store single-channel ECG recordings using the smartphone or tablet.
- Edit user information data associated with the recording.
- Wirelessly transmit ECG recordings to the AliveCor server.
- Access ECG recordings stored on the AliveCor server.
- Print or save the recording in PDF format.
- Request professional clinical interpretation and analysis of your ECG recordings.

After a user has created an account on the *AliveECG* app and received an ECG analysis, the Mobile ECG enables a user to:

- View ECG recordings real-time and after the recording.
- View the output of the Atrial Fibrillation, Normal, and Interference Detectors.

1.1. Indications for Use

The AliveCor Mobile ECG is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Mobile ECG also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Mobile ECG is intended for use by healthcare professionals, individuals with known or suspected heart conditions and health-conscious individuals. The device has not been tested for and it is not intended for pediatric use.

1.2. Contraindications

There are no known contraindications for the Mobile ECG, although care should be taken when considering using the device according to the warnings and precautions below.

2. GENERAL SAFETY PRECAUTIONS

- The device should not be used near water, or in a wet environment.
- Do not use this unit in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- Do not sterilize this unit with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Do not take recordings in a location where the unit will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Signal quality may degrade by detecting signals from other ultrasonic acoustic sources. Do not use the device in close vicinity to other equipment emitting ultrasonic acoustics such as espresso machines, some ventilation systems or another AliveCor Mobile ECG.
- The smartphone or tablet power adapter may degrade signal detection. Do not use the Mobile ECG while charging the smartphone or tablet.
- Disperse any static electricity from your body before using the unit.
- Do not take recordings in a moving vehicle.
- Do not expose the unit to strong shocks or vibrations.
- Do not disassemble, repair, or modify the unit.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use for any purpose other than obtaining an electrocardiogram.
- If the portion of the body where the electrode is applied has too much body fat, body hair or very dry skin, a successful recording may not be possible.
- Some children and adults with very sensitive auditory ability may hear a high-pitched hum or buzz emitting from the device when activated. This is due to normal device function.

3. STORAGE, HANDLING AND MAINTENANCE

Do not store the unit in:

- Locations exposed to direct sunlight,
- Locations subject to high temperatures and high humidity,
- Wet or damp locations where water may get on the unit,
- Dusty locations,
- Near fires or open flames,

- Locations exposed to strong vibration, or
- Locations exposed to strong electromagnetic fields.

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using an alcohol-based sanitizer before each use.
- To prevent potential cross-infection of diseases between users, clean the device using alcohol prior to each use.

4. WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination.
- This device records heart rate and heart rhythm only.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Users should always consult their physician if they notice changes in their health.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- The device has not been tested for use on infants weighing less than 10kg. AliveCor does not recommend using on humans less than 10kg.
- It is not recommended to place a mobile phone directly next to a pacemaker on the chest.
- Do not use this device with a defibrillator.
- AliveCor does not recommend using on individuals with a cardiac pacemaker, ICDs or other implanted electronic devices.
- Do not attempt ECG data acquisition while there is an external microphone plugged in to the smartphone or tablet.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- The heart rate is based on the heart rhythm; therefore the rate is only valid if there is a valid rhythm (QRS complex visible).
- The Interference Detector may incorrectly identify ventricular flutter, ventricular bigeminy and ventricular trigeminy as unreadable. If you have been diagnosed with one or more of these arrhythmias, we recommend turning off the Interference Detector in your Settings.
- AliveCor cannot guarantee that you are not experiencing an arrhythmia or other health condition when labeling an ECG as normal. You should notify your doctor of a

possible change in your health.

5. SET UP THE MOBILE ECG AND TAKE THE FIRST ECG RECORDING

5.1. Decide which smartphone or tablet to use

Your Mobile ECG is compatible with all of the smartphones and tablets listed on AliveCor's website: http://www.alivecor.com/compatibility, including:

- Samsung Note 3
- Galaxy S3, S4 and S5
- HTC One
- Jitterbug Touch 2 and Touch 3

The AliveECG App is compatible with the Android Operating System versions 4.0 - 4.4.

You can use the Mobile ECG with Universal Attachment Plate on all compatible smartphones or tablets as listed on the Compatibility Chart.

The Mobile ECG for Samsung Galaxy S5 can also be used on all compatible smartphones or tablets by removing the oval-shaped Mobile ECG from its case:

1. If the Mobile ECG is currently attached to a Samsung Galaxy S5, remove the Mobile ECG (and case) from the phone.
2. Face the electrodes of the Mobile ECG away from you.
3. Gently push the left side of the Mobile ECG toward you while at the same time gently pulling the left edge of the case away from the Mobile ECG itself.
4. The Mobile ECG should then "pop out" of its case.

5.2. Unpack the AliveCor Mobile ECG

- Remove the Mobile ECG from the box.
- The Mobile ECG with Universal Attachment Plate can be attached to the smartphone or tablet directly or to the case of your choosing (the surface should be smooth and flat).
  - AC-001 - AC-007: With the AliveCor logo right side up, the top of the smartphone or tablet should be on the right.
  - AC-009: With the AliveCor logo right side up, the top of the smartphone or tablet should be at the top.

Caution: The Mobile ECG must be less than 1 foot from the smartphone or tablet to ensure communication between devices.

5.3. Download the AliveECG app

- Using your smartphone or tablet, search for *AliveECG* in the Google Play Store.
- Download and install the *AliveECG* app.

5.4. Set up an AliveCor Account

You will use your AliveCor account to access, print and save your ECG recordings stored on the *AliveECG* app and the AliveCor server. Follow the instructions presented when you open the *AliveECG* app for the first time. You can go back later and change your information if necessary. Signing up for an AliveCor account also enables you to send an ECG for analysis. ECG analysis can be used any time you want a medical professional to interpret your ECG recording and is required if you would like to view your recordings or utilize AliveCor's Detectors.

6. RECORD ECG RHYTHMS USING THE MOBILE ECG

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
- Clean the two electrodes with alcohol-based sanitizer.
- Using your smartphone or tablet, launch the AliveECG app.

Rest two or more fingers (it doesn't matter which fingers) on the Mobile ECG; your right hand should contact the electrode closest to the bottom of the smartphone or tablet, and your left hand should contact the electrode closest to the top of the smartphone or tablet. This is a Lead I ECG.

You may also choose from two other placements:

- For a Lead II ECG, the left knee should contact the electrode closer to the top of the smartphone or tablet and the right hand should contact the electrode closer to the bottom of the smartphone or tablet.
- For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle. The bottom of the smartphone or tablet should be pointing towards the center of the body.

NOTE: You will not be able to view your recordings or utilize any of AliveCor's Detectors until you are under the care of a physician. To gain access to these features, you must create an account on the *AliveECG* app. Your first recording will then be automatically sent for a free analysis by a cardiologist. Once you have received the ECG analysis, you will have access to view that recording and subsequent recordings.

After your display is unlocked, you may swipe your finger across the screen to scroll through each ECG recording. Additionally you can add notes about the recording.

- Tap the "Annotate" icon in the upper right corner to add notes:
  - Medical Professional – Add patient details such as Patient ID, Name, etc.
  - Individual User – Add symptoms and activities
- Tap "Save" to return to the review screen. This information will automatically synchronize with the AliveCor server.

NOTES:

- The Mobile ECG does not require a Wi-Fi or mobile connection to record an ECG and save it to the smartphone or tablet, however it does require one of these to: sync automatically with the AliveCor server, email, or print directly from the *AliveECG* app. If you do not have a Wi-Fi or mobile connection at the time of the ECG recording, you can email or print the data later when you have such a connection and the sync ill happen automatically at that time.
- The Mobile ECG can be used up to a distance of 30 cm (1 ft.) from the smartphone or tablet. Using the Mobile ECG at a distance greater than 30 cm (1 ft.) may lead to communication issues between the devices and your recording may not be successful.
- In order to reduce muscle noise, rest your arms on a flat surface to increase stability while you are recording.
- You must maintain contact with the electrodes for at least 10 seconds for the recording to be saved. If you remove contact after 10 seconds but before the selected recording duration is complete, the ECG will be saved and you will be able to review it.
- The recording must be at least 30 seconds long in order for the Detectors to work.

7. ONCE THE RECORDING IS FINISHED

- Immediately after the recording is complete, you will be prompted to save the ECG. Select your name or 'Other User' if your name is not listed. If you do not wish to save the recording you can select 'Cancel'.
- After selecting your name, the ECG will be saved with your details and you will then be prompted to enter notes and select symptoms and activities. After entering these details, tap 'Save' in the upper right of the screen or 'Cancel' if you do not want to record any notes or symptoms.
- The ECG will then be displayed for reviewing. The review screen allows you to scroll through the ECG by swiping your finger across the screen, and you can pinch and zoom to scale the ECG. There are also options to edit the details and patient information, delete the recording, review previous or next recordings, and to view, email, print and share a PDF report. You can also order an ECG analysis report to have your ECG recording reviewed by a professional, see ECG Analysis for details.

When you have finished reviewing the ECG recording, either press the 'Home' button to exit the app, or press the 'Back' key to return to the 'Record' screen, where you can then record another ECG.

8. SETTINGS AND ADJUSTMENTS

8.1. Recording Adjustments

- **Sweep Speed.** Sweep speed of the ECG in the PDF report can be set to 12.5mm/s, 25mm/s, or 50mm/s. This option is only available to health professionals.

- **Gain**. Gain of the ECG in the PDF report can be set to 5mm/mV, 10mm/mV or 20mm/mV. This option is only available to health professionals.
- **Enhanced Filter.** The Enhanced Filter suppresses noise in the ECG. To enable or disable the Enhanced Filter, tap the review screen, and then tap on the 'Enhanced Filter' switch to toggle the filter ON or OFF.
- **Invert the ECG Recording.** In the event that the Mobile ECG was oriented improperly when the ECG was recorded, it may appear inverted. To change the polarity of the ECG, tap on the center of the review screen, and then tap on the 'Invert' switch to toggle it ON or OFF.

8.2. Adjustable Settings

To access Settings, press the 'Menu' button and select the menu item. Note: For most smartphones and tablets the 'Menu' button is a physical button; however, on some Android smartphones and tablets the Menu button will be an icon in the top right of the screen.

- **Recording Duration.** Recording Duration is the maximum length of time the *AliveECG* app will record a single ECG recording. For example, if the recording duration is set to 30 seconds, the *AliveECG* app will automatically stop recording after 30 seconds of data has been collected. The recording duration can also be set to Continuous, where the system will record as long as the user maintains contact with the electrodes (up to 5 minutes).
- **AC Mains Filter.** The AC Mains Filter removes any mains interference from the ECG; usually you should leave this set to Auto, where the app will select the appropriate frequency of the alternating current (AC) used in your country or region. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz. If required, you can override the auto-selected value and set this to 50 Hz or 60 Hz.
- **Units.** Select this option to set the units for weight and height to Metric (cm, kg) or Imperial (lb., in).
- **PDF Reports.** Sets various options for the PDF report that you can View, Print, Email and share. These settings affect the PDF report only. They do not affect the ECG display on the device or the analysis reports that are provided by our analysis partners.

9. EMAIL, PRINT OR DELETE RECORDINGS

You may email/print recordings from either the *AliveECG* app or your account on the server (www.alivecor.com).

You may print, email or share a PDF report of the recording by tapping the 'Share' icon and choosing your appropriate option.
Note: Support for printing depends on the built-in printing options installed on your smartphone or tablet. Depending on your printer and Android smartphone or tablet, you may need to install a printer app from the Google Play Store.

To email a recording from the server:

1. Go to www.alivecor.com.
2. Click on “SIGN IN” in the upper right corner and enter your email address and password.
3. Select the desired recording by clicking on the appropriate “VIEW ECG” button on the right.
4. Email from your computer as you would any PDF.

To print a recording from the server:

1. Go to www.alivecor.com.
2. Click on “SIGN IN” in the upper right corner and enter your email address and password.
3. Select the desired recording by clicking on the appropriate “VIEW ECG” button on the right.
4. Print from your computer as you would any PDF.

To delete the ECG recording:

1. Tap the 'Trash' icon
2. Confirm that you want to delete the recording.

Deleting a recording from the *AliveECG* app also deletes it from the server. Deleted recordings cannot be retrieved.

10. VIEW PREVIOUSLY RECORDED ECG RECORDINGS ON YOUR SMARTPHONE OR TABLET

NOTE: If you are not enrolled in Alivecor’s ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

11. To see a list of all your saved ECG recordings, tap the AliveECG icon in the top left of the screen and select 'ECG History' from the menu, or from the 'Record' screen swipe the page from right to left.

- To view a recording in the list: Scroll the list and then tap the ECG recording you wish to view. The ECG will then be displayed for reviewing.
- To search for a recording: Tap the ‘Search’ icon and enter the patient's first name, last name, ID, or notes. As you type, the list will be filtered to only show matching items.

12. VIEW AN ECG RECORDING ON THE ALIVECOR SERVER

NOTE: If you are not enrolled in Alivecor’s ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

- On your web browser, go to www.alivecor.com and click on “SIGN IN”.
- Enter your email address and the password you created when you set up your AliveCor account. Click “Sign In”.
- The ECG recordings you collected were automatically synced to the AliveCor server and will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file and can also be viewed in HTML. Click on the “VIEW ECG” button.

- Click the back button in your browser to return to your AliveCor account homepage.

13. ECG ANALYSIS

The *AliveECG* app includes the ability to request professional clinical interpretation and analysis of your ECG recordings. Due to telemedicine restrictions, your location may restrict your ability to use this service. AliveCor does not know your location; it is your responsibility to ensure this service is legal according to your local telemedicine laws. This service is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

To request an ECG Analysis Report:

1. From the History list, select and view the ECG recording that you would like reviewed.
2. Tap the 'Analysis' button
3. Select one of the listed Analysis Report options.
4. If you haven't already entered your name, date of birth and gender, you will be prompted to enter these details. Enter the required details and tap 'Save'.
5. You will then be prompted to select or enter your credit card information. Enter your card details and tap 'Next'.
6. Confirm that the purchase order is correct and tap 'Purchase' to place the order.

Your order is then processed and you will be sent an email confirmation. Another email will be sent when the report is available.

NOTE: The 'Analysis' option is only visible if the analysis service is available in your country.

To view an ECG Analysis Report:

1. Open the notification drawer and select the notification to view the report.
2. Alternatively, from the History list scroll or locate the ECG recording, then tap the report icon, or select the ECG and tap the ECG Analysis button.
3. The analysis report will be listed under 'Analysis Reports', showing the date ordered and the analysis result. If the analysis report has not been received, the report item will indicate 'Analysis in progress'.
4. Tap on the report item to view more details.

NOTE: To view PDF reports on your smartphone or tablet you must have a PDF reader, such as Adobe Reader, built-in or installed on your Android smartphone or tablet. Support for printing depends on the built-in printing options on your Android smartphone or tablet, or you may need to install a printer app from the Google Play Store.

14. DETECTORS (ATRIAL FIBRILLATION, NORMAL, INTERFERENCE)

NOTE: If you are not enrolled in Alivecor's ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

NOTE: Your ECG must be at least 30 seconds long to use the Atrial Fibrillation and Normal Detectors. If an ECG is recorded that is less than 30 seconds, neither the Atrial Fibrillation nor the Normal Detector will display a result.

Atrial Fibrillation Detector

The Atrial Fibrillation (AF) Detector in the *AliveECG* app detects atrial fibrillation in an ECG tracing. After you take an ECG, if atrial fibrillation is detected you will be notified within the app. This finding is not a diagnosis; it is only a potential finding. You should contact your physician to review any ECG recording in which atrial fibrillation was detected, or send it to ECG Analysis. If you are experiencing any symptoms or concerns please contact a medical professional.

The AF Detector monitors for atrial fibrillation (AF) only. It will not detect other potentially life threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present.

The AF Detector only monitors for AF while you are taking a recording. It does not continuously monitor your heart and therefore cannot alert you if AF happens at any other time.

Normal Detector

The Normal Detector in the AliveECG app notifies you when a recording is "normal". This means that the heart rate is between 50 and 100 beats per minute, there are no or very few abnormal beats, and the shape, timing and duration of each beat is considered normal. It is important to remember that there is a wide range of normal variability among different individuals. Changes in the shape or timing of an ECG might be normal for a single individual, but since the AliveCor Mobile ECG is used by a large and diverse population, the Normal Detector has been designed to be conservative with what it detects as normal.

If you have been diagnosed with a condition that affects the shape of your ECG (e.g., intraventricular conduction delay, left or right bundle branch block, Wolff-Parkinson-White Syndrome, etc.), experience a large number of premature ventricular or atrial contractions (PVC and PAC), are experiencing an arrhythmia, or took a poor quality recording it is unlikely that you will be notified that your ECG is normal.

It is also important to note that the Normal Detector looks at the entire signal before determining if it can be declared to be normal. If you experience a small number of PACs or PVCs in a recording of otherwise normal beats in normal rhythm, the Normal Detector will likely declare this recording to be normal.

WARNING: AliveCor cannot guarantee that you are not experiencing an arrhythmia or other health condition when labeling an ECG as normal. You should notify your doctor of a possible change in your health.

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Interference Detector

The Interference Detector in the AliveECG app determines whether a recording can be accurately interpreted or not. After you take an ECG, if interference is detected you will be notified within the app that your recording is "Unreadable" and given some suggestions for acquiring the best quality ECG recording. You subsequently have the option to Save the recording, or Try Again. If the recording can be analyzed, the AF and Normal Detectors will run on the ECG and inform you as described above.

WARNING: The Interference Detector may incorrectly identify ventricular flutter, ventricular bigeminy and ventricular trigeminy as unreadable. If you have been diagnosed with one or more of these arrhythmias, we recommend turning off the Interference Detector in your Settings.

- **What is Atrial Fibrillation?**

  The most common type of non-sinus tachyarrhythmia is atrial fibrillation. In this case, disorganized electrical impulses that originate in the atria and pulmonary veins initiate the electrical activity in the conduction system of the heart. This causes what are commonly termed as "irregularly irregular" heart beats.

  When a heart is in atrial fibrillation, its two upper chambers, the right and left atria essentially quiver, instead of beating efficiently. This does not allow for complete emptying of the atria and thus, blood may become stagnant and create blood clots. This can lead to major problems, namely, strokes, transient ischemic attacks (TIAs), and pulmonary emboli (PEs); depending which chamber of the heart has the blood clot in it.

  Approximately 15 percent of strokes occur in people with atrial fibrillation. As age increases in a population, so too does the incidence of atrial fibrillation, which peaks at about 3-5% in people over the age of 65.

  The most common presenting symptoms of atrial fibrillation are palpitations, dizziness, fast pulse rate, irregularly irregular rhythm, an abnormal heart sound (S1), chest pain, chronic shortness of breath, abnormal jugular venous pressure, fatigue, and impaired exercise tolerance. Other symptoms related to TIAs and strokes may be the initial symptoms of atrial fibrillation.

  Some of the most common causes of atrial fibrillation are long-standing hypertension, congestive heart disease, cardiac valvular lesions, myocardial infarctions, history of coronary artery bypass grafts, hyperthyroidism, alcohol abuse, smoking, diabetes mellitus, and electrolyte imbalances.

- **AF recordings in ECG review screen and History List**

  All tracings analyzed as positive for AF will have “AF” tagged for future review. These tags will be visible on the ECG History List as well as on the ECG review screen.

- **Activation of the AF Detector**

  The AF Detector can be turned on or off in the settings of the *AliveECG* App.

13.1 AF, Normal and Interference Recordings in ECG review screen and History List.

All tracings analyzed as positive for atrial fibrillation, normal or unreadable will have a tag for future review. These tags will be visible on the ECG History List as well as on the ECG review screen.

13.2 Activation of the Detectors

All Detectors, including AF, Normal, and Interference Detectors can be turned on or off in the settings of the *AliveECG* App.

14. ACCESSING HELP

To access Help, press the 'Menu' button and select the menu item. Note: For most smartphones or tablets the 'Menu' button is a physical button on your smartphone or tablet; however, on some Android smartphones and tablets, the Menu button will be an icon in the top right of the screen.

Learn more about using your AliveCor Mobile ECG from the following tutorials included in the *AliveECG* app:

- **Tutorials.** Review these tutorials to learn about to navigate all the features of the app
  - Quick Tutorial
  - Recording an ECG: Tips and information on how to record an ECG.
  - AF Detection: Information about the AF Detector.
  - Sending an ECG for Analysis: Steps through the process of how to send your ECG to one of our partners for professional clinical interpretation and analysis.
  - Reviewing an Analysis Report: A guide on how to view your analysis results.
  - Alternative Recording Positions: The AliveCor Mobile ECG is typically held in your hands to record an ECG. Find out about alternative positions that may provide a clearer recording.
- **Reference.** Learn about ECG analysis; access the user manual, feedback and privacy and terms
  - What is ECG analysis
  - User Manual
  - Privacy Notice

- Terms of Service

15. EDITING USER PROFILE

To access Settings, press the 'Menu' button and select the menu item. Note: For most smartphones and tablets the 'Menu' button is a physical button; however, on some Android smartphones and tablets the Menu button will be an icon in the top right of the screen.

- name@emailaddress.com: Email address of the current AliveCor account.
- User Profile: Details of the account holder.
  - For health professionals, enter your name and organization, which will be stored with each ECG recorded and printed on the reports.
  - For individual users enter your name and other details that will be stored with each new ECG recording.
- Credit Cards: Add or remove credit card details for purchasing ECG analysis reports.
- Sign In/Log out: Allows you to Log in or setup a new AliveCor account, or to log out if you are already logged in.

16. ACCESSING EDUCATION

To learn about different arrhythmias, cardiac anatomy and ECGs:

- Tap the *AliveECG* icon in the top left of the screen., or from the 'Record' or 'History' screen swipe the left edge of the screen to reveal the Navigation drawer.
- Tap Education.

NOTE: The information contained within this section is for educational purposes only. This information has been written and verified by medical professionals.

Do not attempt to use this information to interpret your own ECG. This information is not intended to replace medical advice. Please seek professional medical assistance if you are suffering from any medical problem.

1. PROVIDER DASHBOARD

The Provider Dashboard allows medical professionals the ability to view their patients' recordings automatically from their own account. To create a medical professional account, download the *AliveECG* app and follow the prompts to create a new account.

In order to view a patient's future recordings, you must send them an invite via email. To send an email invite:

1. Go to www.alivecor.com
2. Click on "SIGN IN" in the upper right corner and enter your email address and password
3. Click on "Invite a Patient"
4. Type in the patient's email address (this must be the email address they use for their

AliveCor account)
5. Click “Send Email”

2. ELECTRONIC HEALTH RECORD (EHR) INTEGRATION

Send to EHR: If you are a physician and your AliveCor account has been setup for integration with an Electronic Health Record system (EHR) you can send ECG recordings to your EHR. Tap the 'Send to EHR' icon to send the ECG.

3. TROUBLESHOOTING

Problem	Solution
My Mobile ECG is not working.	Change the battery 1. Expose the battery door at the back of the Mobile ECG: a. Remove the case from the smartphone or tablet by pushing the iPhone through the camera cutout, while peeling back the Mobile ECG from this corner. OR b. Remove the Mobile ECG from the plate: 1. AC-001 - AC-007: Place your thumbs on the electrodes and press down firmly. Turn counterclockwise about 45 degrees to "unlock" the Mobile ECG. Once it's "unlocked" the Mobile ECG can then be lifted out of the plate. 2. AC-009: Use your thumbs to slide the Mobile ECG toward the open end of the plate. 2. Remove the battery door: a. AC-001 - AC-007: Use a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. b. AC-009: Insert a pen, pencil or other similarly shaped object into the cutout next to the battery door to pop the battery door off. 3. Remove the used battery and replace it with a new 3V coin cell battery matched to your model. 4. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable.
I have a lot of artifact, noise or interference in my recording.	Try the following tips for acquiring the best quality ECG recording: • Ensure that the “Enhanced Filter” is on. • Clean the electrodes on the Mobile ECG with alcohol-based sanitizer. • If hands are very dry, use a water-based lotion before recording. • When recording from the hands, relax the arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface and let the Mobile ECG rest on the hands. Do not squeeze the Mobile ECG. • Ensure that your smartphone or tablet is not charging/syncing and you are not using headphones with your smartphone or tablet during the recording. • Make sure that both the smartphone or tablet and the user remain still during ECG recordings. Movement during recordings will cause noise in the tracing. • Make sure Mains Filter is set appropriately for your geographical location. This can be adjusted under the *AliveECG* app Settings. • Try recording from the chest, right under the pectoral muscle in the mid line.
The ECG rhythms appear upside down.	In the future, ensure that the left hand contacts the electrode closer to the top of the smartphone or tablet, and the right hand contacts the electrode closer to the bottom of the smartphone or tablet. To invert a recording on your smartphone or tablet, see “Invert the ECG recording” under “Recording Adjustments”.
I forgot my password and I’m unable to reset it.	To reset your password, go to www.alivecor.com and click on "SIGN IN" in the upper right corner and click on the "Forgot your password?" link below the Password field. On the Forgot Password screen, enter your email address and click Submit. Follow the reset instructions in the email. Please note the reset link contained in the email is only active for a short while.

Problem	Solution
The ECG was lost when I was recording it	Rotating your phone while recording so that the screen “flips” from portrait to landscape mode will automatically stop the recording and that ECG will not be saved. Please do not rotate your phone while recording as this will impact the quality of your recording.
I can’t see my age in the PDF report	If your first and last name are longer than 35 characters combined, your age may be covered due to size restrictions in the PDF report. Please consider using initials for your first or last name in order to ensure you age is visible.
My credit card isn’t being accepted	In rare occasions, the error message indicating that your credit card is incorrect or invalid is automatically cleared by rotating the phone from portrait to landscape or vice versa. Please double check that your credit card information is valid before processing payments.

4. ALIVECOR MOBILE ECG SPECIFICATIONS

Performance Characteristics

ECG Channel .....Single Channel
Input Dynamic Range.....10mV Peak-to-Peak
Memory length .....Practically Unlimited
Recording Format .....Continuous
Shelf Life .....Estimated 2 years

Circuitry

Frequency Response ..... 0.5 Hz to 40 Hz
CMRR..... 76 dB
Input Impedance ..... > 100 MOhm
Differential Range ..... +/- 5 mV
A/D Sampling Rate ..... 300 samples/second
Resolution ..... 16 bit
DC Offset Correction ..... +/- 300 mV

Output

Modulation .....Frequency Modulated Ultrasonic Audio Tone
Center Frequency .....19 kHz
Frequency Deviation ..... 200 Hz/mV

Power Requirements

Battery Type ..... 3V Coin Cell
Battery life ..... min. 200 Hours Operational Time, 12 months typical use

Physical Characteristics

AC-004 & AC-007-UA-A (w/Attachment Plate) 28 grams 89 x 48 x 9 mm 10cm^2 Electrode
AC-009 .....18 grams 82 x 32 x 3.5 mm 9 cm^2 Electrode

Environmental Specifications

Operational Temperature ..... +10 to +45 degrees C
Operational Humidity .....10% to 95% (non-condensing)
Operational Altitude ..... based on your smartphone or tablet specification
Storage Temperature .....-20 to +60 degrees C
Storage Humidity .....10% to 95% (non-condensing)

User Interface

Two stainless-steel electrodes are exposed on the back of the Mobile ECG. These electrodes make contact with the user's skin.

5. EUROPEAN AUTHORIZED REPRESENTATIVE

Obelis SA
BD General Wahis 53
1030, Brussels
Belgium
Tel: +(32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail: mail@obelis.net

6. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.
30 Maiden Lane, 6th
Floor San Francisco, CA
94108 United States
www.alivecor.com

7. ELECTRICAL SAFETY

Guidance and manufacturer's declaration - electromagnetic emissions		
The AliveCor Mobile ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Mobile ECG should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The AliveCor Mobile ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AliveCor Mobile ECG is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration—electromagnetic immunity			
The AliveCor Mobile ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Mobile ECG should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AliveCor Mobile ECG requires continued operation during power mains interruptions, it is recommended that the AliveCor Mobile ECG be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE— U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">The AliveCor Mobile ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Mobile ECG should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 V

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the AliveCor Mobile ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3.5}{V_1}]\sqrt{P}$
$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
 </td></tr>
<tr><td colspan="4">NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AliveCor Mobile ECG is used exceeds the applicable RF compliance level above, the AliveCor Mobile ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AliveCor Mobile ECG.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

AliveCor

Recommended separation distances between portable and mobile RF communications equipment and the AliveCor Mobile ECG

The AliveCor Mobile ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AliveCor Mobile ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AliveCor Mobile ECG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**80 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

8. SYMBOLS USED SYSTEM OR PACKAGE LABELING

	Type CF Applied Part
CE 0459	**European Conformity Mark**
	WEEE – Properly Dispose of Electronic Waste
	Consult Instructions for Use / User Manual
	Manufacturer
	Temperature Limits (Operational)
	Relative Humidity Limits (Operational)
REF	**Model Number**
SN	**Serial Number**
	Direct Current Power Source